PERSPECTIVES AND PRACTICE IN ANTIRETROVIRAL TREATMENT

INTRODUCING ARV THERAPY IN THE PUBLIC SECTOR IN BOTSWANA

CASE STUDY

World Health Organization

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PROFILE OF THE REPUBLIC OF BOTSWANA

Botswana is a large, land-locked country situated in southern Africa with a small population of 1.7 million people. It is one of the least densely populated countries in the world, with a population that is concentrated in the eastern part of the country, along the major roads that link South Africa with the rest of the African continent. Botswana has held free democratic elections since its independence in 1966. It has a stable, growing economy resulting in a GDP per capita of US$ 8196 (Purchasing Power Parity or PPP) in 2001, and is regarded as a transparent and well-governed country in independent, comparative worldwide surveys [1].

Since independence, the country has allocated significant resources for building infrastructure and government services. The public health-care system is free of charge for all citizens, and more than 75% of the population has access to basic health care. Nearly 100% of the children are enrolled in primary schools and 76% of adults are literate [2]. However, the unemployment rate remains high at 19.6%, and an estimated 60% of the population earns less than US$ 2 per day [1, 3].

THE HIV EPIDEMIC IN BOTSWANA

Botswana has one of the highest reported HIV-prevalence rates in the world. The annual HIV Sentinel Surveillance undertaken since 1992 among a representative sample of pregnant women attending antenatal clinics indicates that the prevalence rate peaked at 38.5% in 2000 and declined to 35.4% in 2002 [4]. The average prevalence rate among clients attending 1 of the 16 free-standing voluntary counselling and testing centres has been reported as 41.4% [5].

The impact on society is reflected by a 62% increase in annual mortality rates in the 2001 census data compared to 1991 and a decrease in estimated life expectancy from one of the highest in Africa at 66.9 years for women in the 1990-1995 period to 30 years expected in the 2005-2010 period [6, 7].

RESPONSE TO THE HIV EPIDEMIC

Since 2000, the Government of Botswana has demonstrated political leadership by making HIV/AIDS a priority for the country and adopting a compelling, long-term vision to have no new infections from HIV by the year 2016, when Botswana will celebrate 50 years of independence. The President of Botswana, Festus Mogae, has stated publicly, "We are threatened with extinction. People are dying in chillingly high numbers. It is a crisis of first magnitude" [8].

Botswana realized that the epidemic had reached such a magnitude that it could not be faced alone without outside support and innovative new ways to address the crisis. This resulted in the establishment of public–private partnerships such as the African Comprehensive HIV/AIDS Partnerships (ACHAP) between the Government of Botswana, the Bill & Melinda Gates Foundation, the Merck Company Foundation and the pharmaceutical company Merck, Sharp & Dohme (MSD). The objectives of this partnership, which started in July 2000, are to support national coordination mechanisms; to build sustainable capacity in health-care structure and systems; to support the development and implementation of a comprehensive HIV/AIDS strategy integrating prevention, care, treatment and support; and the long-term mitigation of the impact of the HIV epidemic.

The Government has acknowledged the need to build on the strategic plans of the past by developing a National Strategic Framework 2003-2009 that facilitates the implementation of HIV/AIDS initiatives. The Government sought to mobilize districts and other sectors to enable them to develop their own strategic plans and facilitate the implementation of their HIV/AIDS-related activities. As nationwide mobilization does not occur overnight, the Government decided early in 2001 to initiate in parallel a rapid assessment of the feasibility of making antiretroviral therapy available in the public sector.

The rationale for this decision was based on consideration of four compelling reasons [9]:

- *Humanitarian.* Treatment is essential for people already infected, since the vast majority of them will die without it.
- *Prevention.* Treatment is necessary to optimize prevention efforts. Access to treatment can be an incentive for an individual to take an HIV test, which enables primary prevention for those uninfected and antiretroviral treatment for those infected. Effective antiretroviral therapy lowers the viral load and reduces the likelihood of HIV transmission to others.
- *Save children and the fabric of society.* With more adults dying, the number of AIDS orphans will increase and result in a demographic shift that may contribute to increased societal political instability and violence.
- *Economic development.* Without treatment many adults will die in the prime of their working lives, taking with them the skills and knowledge base that are necessary for human and economic development.

The ACHAP was commissioned by the Government to perform the feasibility study. With support of the *pro bono* services of the international management consultancy firm McKinsey & Company, a multisectoral team was formed, consisting of 20 members responsible for data collection, situation and gap analysis and the development of an overall plan to ensure the successful launch of antiretroviral therapy in Botswana. Data collection and analysis included interviews with local and international community leaders, medical personnel and medical aid organizations, review of clinical and hospital records and broad consultation with local key stakeholders. It was decided to adopt a demand–supply model and use an approach that combined clinical research, public health and business principles to answer three key questions:

- What is the estimated number of patients who would require ARV therapy?
- How well is the country situated to be able to provide ARV therapy from a human, financial and physical resource perspective?
- What is the recommended way to tackle the issues and logistics associated with providing effective ARV therapy nationwide?

The team began the assignment at the end of April 2001 and presented the key results and recommendations to the cabinet and all key stakeholders towards the end of August 2001.

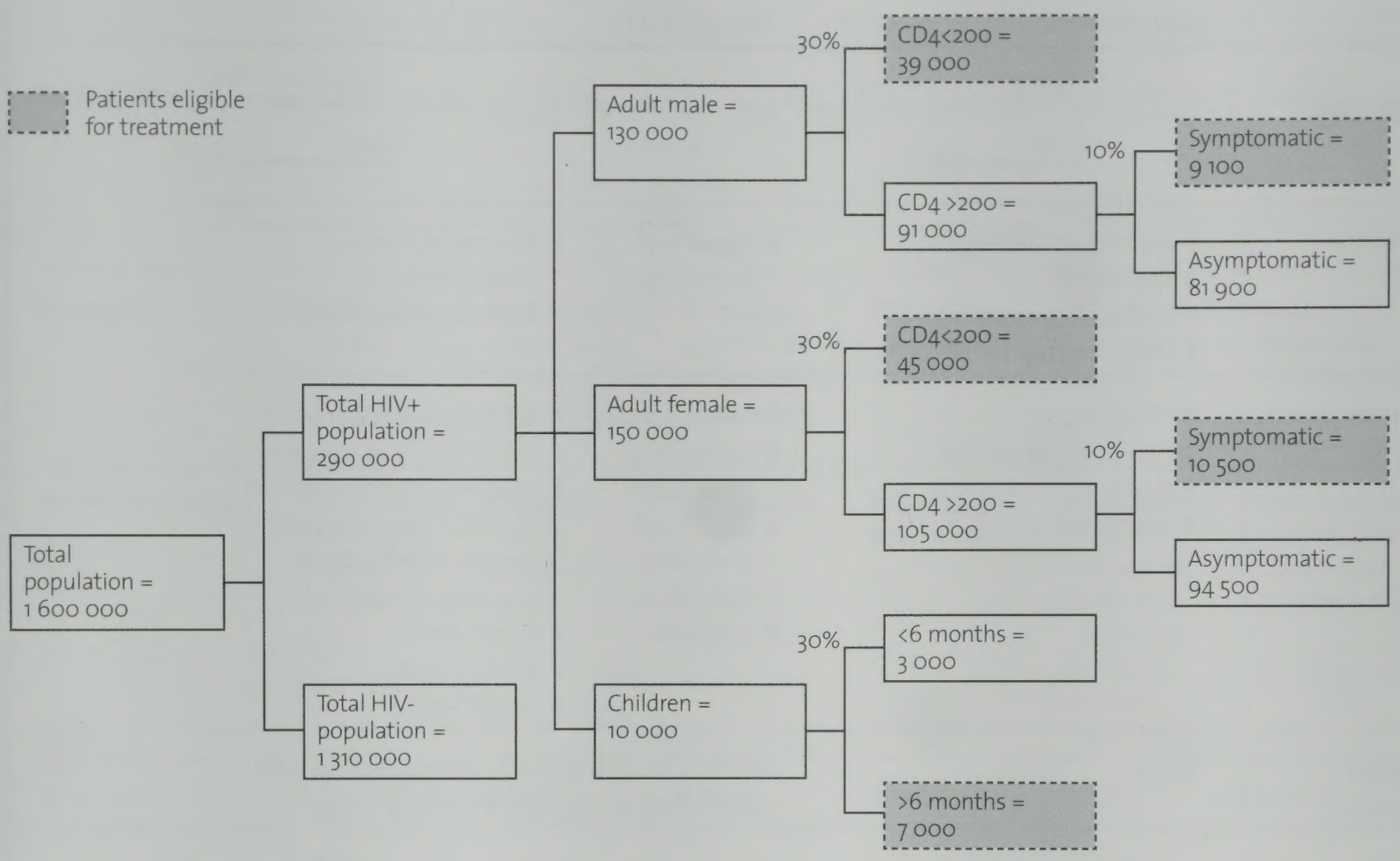
ESTIMATION OF THE NUMBER OF PATIENTS REQUIRING ARV THERAPY

Numerous issues needed to be addressed in assessing demand. Neither HIV infection nor AIDS are notifiable diseases in Botswana. In addition, it appeared that patient records and death certificates very seldom report HIV as the leading cause for consultation, hospital admission, or death. In many cases, HIV-related pathology can be assumed when patients are labelled as suffering from AIDS-defining illness such as pneumonia, weight loss, generalized immuno-suppression, certain infectious diseases and tuberculosis.

Given the large reported prevalence, it was likely that many HIV-positive individuals would not be identified since it was assumed that less than 10% of the general population was aware of its HIV status and many symptomatic patients were not properly diagnosed.

Based on the estimated prevalence and the hypothesis that approximately 30% of the HIV-positive population would have a serious immunodeficiency as reflected by a CD4 count below 200, and 10% of the HIV-positives with a CD4 count above 200 would have AIDS-defining illness, it was estimated that the so-called "latent demand" for ARV therapy in the year 2001 was about 110 000 people (Figure 1). This number was expected to grow in a linear way to 260 000 by the year 2005, driven by the dynamics of the HIV epidemic and assuming that all patients would be treated as soon as they become clinically eligible. Given that most people did not know their HIV status, it was unlikely that this whole patient load would present at once.

Figure 1: Estimated number of patients requiring ARV therapy

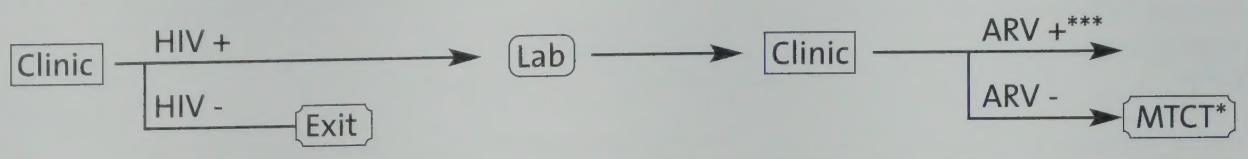


* Clinical subcommittee recently recommended treating all HIV+ pregnant women with HAART. If this recommendation is accepted it would increase demand.

Assessment of required resources to introduce ARV therapy

From a supply perspective, it was necessary to assess and evaluate all the steps of the continuum of care from pre-test counselling to adherence management combining local practices and guidelines with international models. Time allocation, personnel and space requirements were assessed for each step. Detailed patient flow analysis was done to assess the resource requirements for newly diagnosed patients as well as existing patients, and patients presenting with complications such as minor side-effects, drug-related toxicities or resistance, and thus requiring additional adherence counselling (Figures 2, 3, 4).

Figure 2: Patient flow for enrollment to the ARV Program

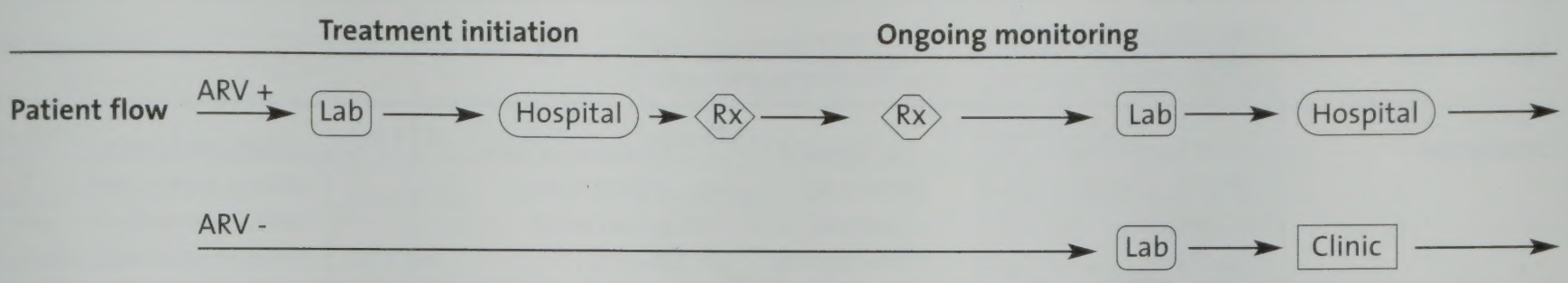
	HIV diagnosis	ARV eligibility	
Patient flow			
Description	◗ Pre-test counseling ◗ Rapid test ◗ Post test counselling ◗ HIV+ referred to blood lab	◗ Blood test with CD4	◗ Review of labs and clinical exam to determine eligibility
Resources required	◗ Clinic doctor ◗ Clinic test counselor ◗ Nurse ◗ Rapid test	◗ Phlebotomist ◗ Laboratory technician ◗ CBC** and chemistry ◗ ELISA test ◗ CD4 test	◗ ARV eligible referred to blood labs and hospital ◗ ARV non-eligible referred to MTCT program and community NGOs for ongoing counseling ◗ Clinic doctor ◗ Clinic nurse ◗ Social worker
TB model differences	None	All HIV + and TB patients are eligible for ARV and therefore skip 'ARV eligibility' steps	
In patient differences	HIV diagnosis conducted in ward with hospital doctor and nurse	All inpatients with AIDS defining conditions eligible for ART and therefore skip "ARV eligibility" steps	

* Prophylactic dosing administered to all children

** CBC – complete blood count

*** ARV+ and ARV- refer to the outcome of assessment of eligibility to treatment based on clinical and diagnostic criteria. Asymptomatic adult patients with CD4>200 and children < 6 months will enter the ARV– arm and are possibly eligible for PMTCT if pregnant or are being followed up in six months intervals or earlier – in case of symptoms. Remaining patients (CD4<200 and symptomatic patients - WHO stages 3 and 4) will be enrolled to ARV treatment (ARV+ arm).

Figure 3: Patient flow for ARV therapy without complications



Description	◗ Blood test for VL baseline	◗ Full physical exam and choice of drug regimen	◗ Provision of ARVs and drug-specific counseling	◗ Rx refill (monthly)	◗ Blood test prior to doctor visit	◗ Medical check-up at - 6 weeks and 3 months for ARV+, - 6 months for ARV
Resources required	◗ Phlebotomist ◗ Lab technician ◗ VL test	◗ Hospital doctor ◗ Hospital nurse	◗ Pharmacist	◗ Pharmacy ◗ Technician	◗ Phlebotomist ◗ Lab technician ◗ CBC and chemistry ◗ CD4 test ◗ VL test (ARV+ only)	◗ Hospital doctor ◗ Hospital nurse ◗ Clinic doctor ◗ Clinic nurse
TB model differences	◗ Additional lab tests CBC, chemistry, CD4 (due to skip over of last step)	◗ None	◗ None	◗ None	◗ None	◗ None
In-patient differences	◗ Additional lab tests CBC, chemistry CD4 (due to skip over of last step)	◗ None	◗ None	◗ None	◗ None	◗ None

Total time invested over year one for patient on ARV therapy	
Doctors	5.5hrs
Nurses	7.7hrs
Test counsellors	6.3hrs
Pharmacists	0.6hrs
Pharmacy technician	2.0hrs
Phlebotomists	2.3hrs

VL – viral load

Figure 4: Patient flow for ARV therapy with complications

	Minor side effects	Drug-related toxicities/resistance		Additional pharmacy support
Patient flow	→ Clinic →	→ Hospital →	Rx →	→ Rx →
Description	Treatment of side effects such as nausea or diarrohea	Full physical exam and choice of new regimen	Provision of new regimen and guidance on dosing	Additional time to discuss dosing and adherence (four times in year one)
Resources required	Clinic nurse	Hospital doctor Hospital nurse	Pharmacist	Pharmacist
TB model differences	None	None	None	None
In patient differences	Occurs at hospital out-patient department with hospital nurse	None	None	None
Annual occurrence (% of total patients)				
ANC patients	40	20		50
TB patients	40	40		50
Inpatients	80	40		50

Needs like training, testing and laboratory capacity, requisite drug procurement, distribution and security, counselling infrastructure and community mobilization, as well as space and information technology (IT) were also assessed. The high level of staff shortages and vacancies prompted an assessment of efficiency improvement measures such as task re-distribution, utilizing lay counsellors, interpreters and phlebotomists, and introducing electronic communication tools. It was obvious that treating the whole group of "latent demand" patients would require a significant increase in available resources in terms of human resources, laboratory capacity and space (Figure 5).

Figure 5: Increase in available resources at national level for treating all patients requiring ARV

Key resource	National capacity	Incremental ARV capacity required**	National capacity*** increase for ARVs
Doctors*	514 FTEs	150 FTEs	29%
Nurses*	4416 FTEs	330 FTEs	8%
Pharmacists	29 FTEs	50 FTEs	179%
Pharmacy technicians	164 FTEs	90 FTEs	56%
Lab Technicians*	165 FTEs	190 FTEs	115%
Community**** Health Workers	–	1000 FTEs	–
ELISA tests	1464 per day	700 per day	48%
CD4 tests	100 per day	2 500 per day	2500%
Viral load tests	–	2 600 per day	–
Storage	10 m^3	42 m^3	420%

FTE – full time quivalents

* At clinics and hospitals, including specialists and medical officers treating both adults and patients
** Excluding requirements to treat initial TB and Antenatal clinic (ANC) population
*** Includes hospital staff only
**** Community health workers in Botswana have not been involved in intramural or out-patient care related to ARV treatment. They report to a different sector ministry and concentrate on home based care and health education.

Source:National manpower plan; team analysis

Launch strategy of ARV therapy

It was recommended that the potential demand for ARV therapy needed to be managed in the first year by a combination of geographical and clinical criteria. The intake of patients was limited to the catchment areas of four of the thirty-two public hospitals of Gaborone, Maun, Serowe and Francistown and limited to four distinct patient groups using the principles of: "treat the sickest", public health considerations, cost-effectiveness and "secure the family". The four patient groups are:

- pregnant women with AIDS-defining illness and/or CD4 counts below 200, and qualifying partners fulfilling the same criteria;
- all HIV-infected children older than six months of age who were in-patients;
- all HIV-infected TB patients; and
- all adult in-patients with AIDS-defining illness and/or CD4 counts below 200.

Using the data on local prevalence, HIV-testing, consultation and referral patterns, it was estimated that the total potential demand in the catchment areas of the 4 sites would be around 19 000 patients. This patient number became the stretch target for building the resource requirements for ARV therapy along six work streams in the first year of the programme. Further expansion of the programme would be guided by the experiences on uptake and problems encountered. Expansion could occur according to geographical criteria to other catchment areas, according to clinical priorities, or a combination of both.

The anticipated activities by work stream were as follows:

1. Recruitment and training of health-care workers. It was noted that 62% of the required head count for which additional budget allocation was not required, could be addressed if vacant positions in the health-care system were filled. Training needs were addressed by developing distant-learning modules on diagnosis, treatment of HIV/AIDS concentrating

on issues related to ARV therapy, and expand existing international collaborative initiative with clinical preceptors.(refer p.9)

2. Testing and laboratory capacity. It was decided to accelerate the planned expansion from 3 to 16 stand-alone testing and counselling centres, and establish two reference laboratories for CD4 and VL testing.

3. Counselling and community mobilization. Great efforts were allocated to develop written and visual educational tools for patients, family members, and the wider communities. Counsellors in institutions as well as lay counsellors were mobilized. Support groups for people living with HIV/AIDS and faith-based organizations were strengthened.

4. Drug distribution. Only minor, low-cost changes were required to improve the integrity of the distribution chain.

5. Space. Due to the anticipated shift from in-hospital care to out-patient care, additional space was required for consultation, counselling, waiting rooms, dispensing and administrative facilities. It was decided to build 20 portable units rapidly with a total surface of 6 400 m^2.

6. IT-based patient management system. As none of the existing health care facilities was using IT-based solutions, it was decided to start with a manual, paper-based system that could evolve into an IT-based solution over time. Significant efforts were required in terms of training and building IT-infrastructure at the facilities.

Multiple risks were assessed and anticipated, including: lower and greater patient loads than anticipated, breakdown of the treatment supply chain, drug distribution, clinical response issues such as adverse effects, toxicities and development of rapid resistance, and adherence management.

To prevent duplication of efforts, and mitigate the high level of risk and the degree of uncertainty, it was recommended that coordinating bodies responsible for operational issues, policy issues and decision-making be established and embedded as much as possible in existing structures and systems. Operational management and monitoring would be ensured by a multi-sector ARV team located in the Ministry of Health. Development of policies and guidelines on ARV therapy was done by the Clinical Advisory Committee on the Management of HIV/AIDS, a group of local experts selected from the private and public sector. Decision-making on policies, financial considerations, and roll-out plans were done by the National AIDS Council and directly by cabinet.

Treatment regimens. Recommended treatment regimens of HAART in Botswana as suggested by the Clinical Advisory Committee, follow a three-line approach [10]:

- **Starting regimen.** Zidovudine (ZDV) plus lamivudine (3TC) plus efavirenz (EFV). For children below five years and pregnant women or women in whom pregnancy is likely to occur, efavirenz is replaced by nevirapine.
- **Second line regimen.** Didanosine (ddI) plus Stavudine (d4T) plus Nelfinavir (NFV).
- **Third line regimen.** Ritonavir (RTV) plus Saquinavir (SQV).

Cost estimates

The estimated costs of the ARV programme at the start of 2002, based on a target of 19 000 patients would be US$ 28 million equating to a cost per patient of US$ 1500 per year. Approximately 46% of this cost would be attributable to drug procurement and distribution, 23% to building testing facilities and purchasing testing reagents, 21% to human resources and training, and 10% to information, education, and communication, IT and physical space. It was expected that reductions in costs could be achieved by further reduction in drug prices, changing testing protocols or employing more affordable testing methods, implementing staff efficiencies, and mobilizing communities and family members for supporting adherence to therapy.

The introduction of ARV therapy

The programme started in January 2002 in one site and expanded to the four initial sites by July 2002. The enrolment of new patients was much lower than anticipated, which was likely a result of the low percentage of the population aware of its HIV status. The patients that initially enrolled at each site were in general the very sick, reflecting the advanced stage of the epidemic, the natural tendency of people to wait until symptoms emerge before seeking health services, and sociocultural factors such as denial and stigma. The enrolment of many very sick patients requires a high intensity of resources and creates a significant burden on the ARV programme. Anecdotal evidence indicates that the time and resources required for patients with advanced AIDS is more than five times higher compared to asymptomatic patients with CD4 < 200.

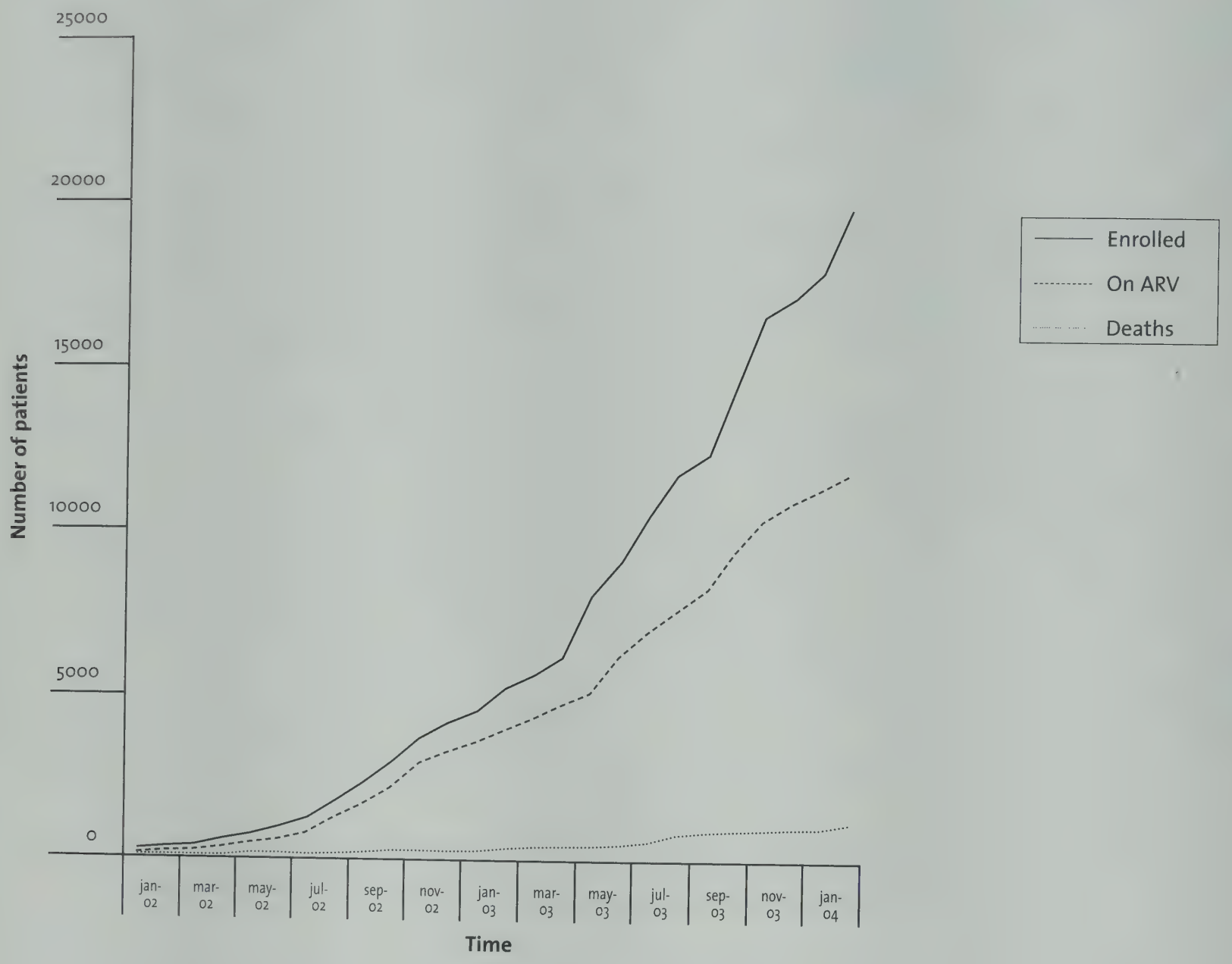
Table 1: Patient Enrolment by February 2004

Site	Launch Date	Tested with: CD4<200 or AIDS Defining Illness or children	Patients on ARV	Deaths on ARV	% Deaths on ARV
Gaborone	Jan 21, 2002	9,366	4,834	490	9%
Francistown	May 13, 2002	4,182	3,040	243	7%
Serowe	May 13, 2002	2,324	1,384	139	9%
Maun	July 10, 2002	1,265	838	137	14%
Jwaneng	April 1, 2003	870	448	27	6%
Orapa	May 1, 2003	447	262	16	6%
Tutume	Oct 8, 2003	254	177	19	10%
Molepolole	Oct 9, 2003	264	115	8	7%
Mahalpye	Oct 13, 2003	462	419	22	5%
Kanye	Oct 23, 2003	241	143	5	3%
Total Public		**19,675**	**11,660**	**1,106**	**9%**
Private Sector (AFA, BOMAID & Debswana)			6,139		
Public+ Private Total			**17,799**		

Source: Botswana National ARV Team Statistics, AFA, BOMAID and Debswana communications

The decision to launch new sites (Table 1) was determined by the operational readiness as verified with a minimum requirements check list. Each site experienced a typical sigmoid shaped "learning curve" characterized by a long starting phase with enrolment of a small number of patients, followed by a rapid uptake and flattening out. The driving force for this phenomenon appeared to be the confidence level, commitment and experience of the local treatment teams. It is our observation that clinical preceptors can play a major role in catalysing this process. The "Preceptorship" program involves the secondment of senior HIV clinicians and nurse counselors to a new site, to provide clinical leadership in ARV therapy, mentorship and management support, for a minimum of 3 months. The consolidated curve of enrolment shows the same sigmoid curved shape (Figure 6).

Figure 6: Patient enrollment and monitoring statistics by February 2004



Source: Botswana National ARV Team Statistics, ACHAP M&E Unit and Botswana Harvard Partnership Abstract Data

Table 2

Monitoring Statistics

Indicator	Result
Female:male	64:36(%)
Median baseline CD4 count	86
Median CD4 increase after 15 months	220
Mean weight gain after 15 months	10 kg
Patient follow-up	>90%
Adherence (zero tolerance)	85%
Toxicity requiring medication switch	< 7%
Complete VL suppression after 6 months	85%
Deaths after treatment initiation	9%

VL – viral load

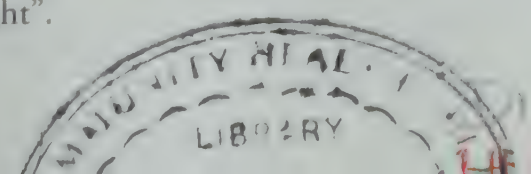
Outcomes

A cohort of approximately 700 patients has been followed up for more than 15 months, demonstrating good clinical outcome as reflected by a median increase in CD4 count of 220 and a mean weight gain over the same period of 10 kg (Table 2). The average death rate after treatment initiation is 9%, varying between sites from 3% to 14%. Although the mortality is significantly higher for patients with a CD4 count below 25, the death rate seems independent of the immunological status at enrolment for patients with CD4 count above 25. Less than 2% of enrolled patients consisted of pregnant women, and referral from mother-to-child transmission programs to ARV treatment programs for expectant mothers qualifying for HAART seldom occurred.

Table 3: Average diagnostics done per patient per year

Test	Frequency in 1 year
Viral load	5
CD4	5
Chemistry	5
Hematology	5
Hepatitis	1
Syphilis	1
Resistance	0

Overall, less than 10% of patients have been lost to follow-up, with good adherence of 85% in terms of self reporting, pill counts, and attending scheduled appointments. These qualitative data are confirmed in complete viral load (VL) suppression after six months of 85%. Diagnostic laboratory tests were requested more frequently than advised in the national guidelines. This was related to the advanced disease status of many patients as well as the desire of many doctors to confirm clinical symptoms with quantifiable data (Table 3). Viral load assessment was appreciated as a good surrogate indicator of adherence to treatment, facilitating the possibility of delegating follow-up visits to counselling and nursing staff. One of the leading doctors in Botswana, Dr Nwape expressed his thoughts on this as "Thanks to viral load assessments, I can sleep at night".



Each new site experienced the same "teething problems" related to coordination, internal communication and management. The minimum requirement checklist proved to be of limited value where issues not immediately obvious such as leadership style, sense of accountability and motivation of local staff had impact on progress. We recommended that the programme be expanded as broadly as possible after the initial pilot. The ARV programme in Botswana was extended to 10 sites during 2003 and will be introduced in all 32 public hospitals by the end of 2004.

Next steps

Routine testing was introduced in January 2004. Despite some initial logistic and monitoring problems, four months of data (January – April) were collected from 18 hospitals. A total of 6,384 people were offered HIV-testing, of which 5,543 (87%) accepted to be tested routinely, while the remaining 14% "opted out". The large majority of people being tested were diagnosed as being HIV-positive (3,460 or 62%), of which 10% or 545 people were eligible for ARV treatment, and 201 or 6% died before referral.

The major barrier for expanding access to ARV therapy is the inadequate capacity to rapidly increase the number of people aware of their HIV status through existing stand-alone testing and counselling services. It is estimated that during 2003 about 50 000 people were tested for HIV in Botswana through testing and counselling or for diagnostic purposes, which is less than 5% of the population. Introducing integrated testing and counselling services could double the annual number of people tested for HIV, but would only have a limited impact on enrolment of new patients. Given these circumstances, Botswana considered and introduced routine HIV-testing with an opt-out possibility to all who come for treatment at hospitals and clinics from January 2004 [11]. It was felt that routine HIV testing is an ethically defensible public policy option, since it promotes the common good and individual rights in the context of an overwhelming public health emergency [12, 13].

Estimates suggest that traditional health practitioners are very commonly used in developing countries [14, 15]. A survey undertaken in December 2002 in Botswana demonstrated that there are approximately 100 times more traditional practitioners compared to biomedically trained doctors [16]. The same survey indicated that approximately 50% make a diagnosis of AIDS through bone-throwing, prayer or identification of signs and symptoms, about 35% treat AIDS with herbs and traditional medicines and 17% of traditional practitioners would advise patients enrolled in ARV therapy to discontinue treatment. An overwhelming majority of

traditional practitioners expressed interest in collaborating more closely with the ARV programme to provide a positive contribution in terms of adherence management and counselling. Integrating traditional health-care systems with ARV access programmes could make an important contribution to improving adherence and reducing the risk of resistance to treatment.

Strengthening community-based support groups, enhancing network of people living with HIV/AIDS and mobilizing of local faith-based organizations will be critical to creating an enabling environment for adherence to ARV treatment.

The priority of the ARV programme is saving and improving the quality of human lives. In a longer-term perspective it is important to optimize the chances to make treatment and prevention mutually reinforcing elements of a comprehensive strategy. Several opportunities are being explored in Botswana. They include strengthening the linkages with the mother-to-child transmission programmes as life-long ARV access provides an additional incentive for mother and her partner.

Partner notification and contact tracing are effective public health interventions in other infectious diseases and should be considered and reinforced. Partner protection can be introduced as a driver for behaviour change of enrolled patients, complementing current efforts that concentrate on condom distribution and support. Epidemiological models suggest that one HIV-positive individual infects an average of five other people in southern Africa [17]. Reducing unsafe sexual practices among this target group seems a rational intervention in reducing HIV transmission. Lastly, there is some evidence that reduced overall viral load in the community reduces HIV transmission [18, 19].

As of September 2004 there were 21,276 people on antiretroviral therapy in the public sector programme. In the private sector, another 6,900 people are on treatment bringing the number of people on treatment in Botswana to a total of 28,167.

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